UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

IN RE NEW ENGLAND COMPOUNDING PHARMACY, INC. PRODUCTS LIABILITY LITIGATION	)	
THIS DOCUMENT RELATES TO:	)	**MDL No. 2419**
All Cases Against Saint Thomas Outpatient	)	**Dkt. No. 1:13-md-2419 (RWZ)**

PLAINTIFFS' STEERING COMMITTEE'S MEMORANDUM OF FACTS AND LAW SUPPORTING MOTION FOR PARTIAL SUMMARY JUDGMENT REGARDING PRODUCT LIABILITY CLAIMS AGAINST SAINT THOMAS OUTPATIENT NEUROSURGICAL CENTER

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The Plaintiffs' Steering Committee respectfully submits this memorandum in support of their Motion for Partial Summary Judgment Regarding Products Liability Claims against Saint Thomas Outpatient Neurosurgical Center (Doc No. 2300).

INTRODUCTION AND SUMMARY OF ARGUMENT

The Tennessee Plaintiffs assert product liability claims pursuant to the Tennessee Products Liability Act of 1978, Tenn. Code Ann. § 29-28-101 *et seq*. That statute authorizes claims for strict tort liability against sellers and distributors of defective or unreasonably dangerous products if and when a product manufacturer is judicially declared insolvent.[1]

By authorizing strict product liability claims against product sellers and distributors if and when product manufacturers are insolvent, the Tennessee legislature furthered important public policy: the risk that a product maker will become defunct rightfully falls upon those who choose to do business with product manufacturers who later prove financially unsound. As the Tennessee Supreme Court recognizes, that risk should not fall upon innocent tort victims who are powerless to protect themselves.

On August 20, 2014, this Court ruled that the Tennessee Plaintiffs are allowed to proceed with claims for strict product liability against the Tennessee Defendants separate from their claims under the Tennessee Healthcare Liability Act.[2] This Court found that the Tennessee Healthcare Liability Act does not prevent the Tennessee Plaintiffs from asserting claims for strict product liability under the Tennessee Products Liability Act.[3]

Through the present motion, the Tennessee Plaintiffs request entry of partial summary judgment establishing: (1) that joint and several liability applies to Plaintiffs' strict product liability claims; and (2) that the Defendant Saint Thomas Outpatient Neurosurgical Center ("Saint Thomas Neurosurgical") falls within the broad statutory

[1] Tenn. Code Ann. § 29-28-106(5).
[2] Memorandum of Decision entered August 29, 2014, Doc. No. 1360 at 30-31.
[3] *Id.* at 25-31.

definition of "seller" contained in the Tennessee Products Liability Act. In other words, fault cannot be attributed separately at trial to parties within the "chain of distribution."

Joint and several liability applies, under the controlling precedent articulated by the Tennessee Supreme Court in *Owens v. Truckstops of America*, 915 S.W.2d 420 (1996), when plaintiffs assert claims for strict product liability. Manufacturers, sellers, and distributors of defective products, as well as all parties within the "chain of distribution," are jointly and severally liable.[4] In such cases, fault at trial must be assigned to the product as a single unit or share.[5] Fault cannot be assigned separately to parties involved with making, testing, marketing, distributing or selling the product.

The Tennessee Supreme Court based its ruling on the public policy underpinning strict product liability claims, *i.e.* that innocent tort victims "who are powerless to protect themselves" should not bear "the burden of loss" resulting from a defective product.[6] That burden should be borne jointly by those parties involved in bringing the product to the consumer in the marketplace.

The Tennessee Products Liability Act defines the term "seller" to include "a retailer, wholesaler, *or distributor*, and means <u>any individual or entity</u> engaged in the business of selling a product, <u>whether such sale is for resale, or for use or consumption</u>."[7] Based upon the testimony of several Tennessee Defendants, it is undisputed that Saint Thomas Neurosurgical distributed methylprednisolone acetate ("MPA") to patients. The undisputed facts likewise demonstrate that Saint Thomas Neurosurgical meets the statutory definition of "seller."

Saint Thomas Neurosurgical operates a high volume pain clinic that distributes hundreds of vials of MPA to patients each month. In addition, undisputed testimony of the

[4] *Owens v. Truckstops of America*, 915 S.W.2d 420, 430-433 (Tenn. 1996).
[5] *Id*.
[6] *Id*.
[7] Tenn. Code Ann. § 29-28-102(7).

clinic's Facilities Director, the Defendant Debra Schamberg, conclusively establishes that Saint Thomas Neurosurgical actually sells epidural steroids to patients. Defendant Schamberg unequivocally testified that "Saint Thomas Neurosurgical provides epidural steroids to patients in exchange for money."[8]

When Saint Thomas Neurosurgical sold and distributed contaminated MPA to patients, it billed for the epidural steroid injections separately from the services of the physician who injected the medicine. It sent invoices charging for steroid injections separate and apart from invoices sent by the Defendant Howell Allen Clinic (the neurosurgery group that owns ½ of Saint Thomas Neurosurgical) for the services of physicians who administered the steroids to patients.

Saint Thomas Neurosurgical is a for-profit entity. It does not give steroids to patients for free. Its status as a seller is beyond dispute. In fact, the clinic's written contracts with various payers, such as Blue Cross Blue Shield of Tennessee, expressly state that payments received by Saint Thomas Neurosurgical include compensation for drugs provided to patients.

Saint Thomas Neurosurgical's status as a seller is further demonstrated by a letter that it sent to NECC in October of 2012, shortly after news of the fungal meningitis catastrophe became public. In that letter, Saint Thomas Neurosurgical asserted that NECC breached its warranty of "merchantability," and it stated that the subject steroids "are no longer fit for use/sale due to contamination." Based upon those undisputed facts, this Court should rule that Saint Thomas Neurosurgical is a seller or distributor of MPA, and therefore meets the broad statutory definition of "seller" as articulated in Tenn. Code Ann. § 29-28-102(7).

Saint Thomas Neurosurgical selected NECC as its supplier of choice for injectable steroids. Patients played absolutely no role in that selection. They relied exclusively upon Saint Thomas Neurosurgical to make a safe choice. This Court should follow the

[8] See **Exhibit 1**, Deposition of Debra Schamberg at 55.

controlling precedent of *Owens* and apply joint and several liability to Plaintiffs' strict product liability claims.

MATERIAL UNDISPUTED FACTS

This litigation arises from a fungal meningitis outbreak caused by contaminated steroids compounded in Massachusetts. Numerous clinics across the United States sold and distributed contaminated steroids to patients. To date, more than 750 people suffered fungal meningitis, fungal infections and/or abscesses as a result of the contaminated steroids.[9] At least 64 people died.[10]

The catastrophe impacted Tennessee with particular severity. The tainted steroids sickened 153 Tennesseans and killed 16 Tennesseans.[11]

A. Compounding Pharmacies Are Generally Not Regulated by the FDA.

According to the FDA, traditional compounding is the extemporaneous combining, mixing, or altering of ingredients by a pharmacist in response to a physician's prescription.[12] Compounded drugs are mixed in response to a physician's prescription in order to create a medication tailored to the specialized needs of an individual patient.[13] Traditional compounding is used typically to prepare medications that are not available commercially, such as a drug for a patient who is allergic to an ingredient in a mass-produced product, or diluted dosages for children.[14]

Because the law requires that compounding pharmacies compound specific medications in response to individual prescriptions, compounding pharmacies should not produce

[9] See **Exhibit 2**, *U. S. Centers for Disease Control and Prevention*, http://www.cdc.gov/hai/outbreaks/meningitis-map-large.html.
[10] *Id.*
[11] *Id.*
[12] See **Exhibit 3**, Exhibit 33 to Deposition of Debra Schamberg, R.N. ("Schamberg Dep."), *p. 2*,, and See **Exhibit 4**, Saint Thomas Outpatient Neurosurgical Center LLC, et al's Responses to the Plaintiffs' Steering Committee's First Set of Requests for Admissions and Corresponding Interrogatory ("PSC's Requests for Admissions") No. 7.
[13] *Id.*
[14] See **Exhibit 5**, Exhibit 32 to Schamberg Dep., p. 1, and **Exhibit 4**, PSC's Requests for Admissions No. 12.

medications in bulk for mass distribution.[15] Accordingly, the FDA did not regulate compounding pharmacies to the same degree as pharmaceutical companies.[16] The FDA generally leaves regulation of compounding pharmacies to state pharmacy boards.[17]

B. Risks of Pharmacy Compounding Known Before Meningitis Catastrophe.

The serious risks of pharmacy compounding were the subject of considerable public discussion in the pharmacy community and the medical community before the subject meningitis catastrophe. For example, in 2002 (ten years before the meningitis catastrophe), the CDC published a report regarding at least two cases of fungal meningitis arising from contaminated medication used in epidural injections. That report concluded: "purchasers of pharmaceuticals should determine if supplies are provided from a compounding pharmacy that . . . follows appropriate measures to ensure that injectable products are free of contamination."[18]

On March 24, 2005 (seven years before the meningitis catastrophe), *USA Today* published a front page article with the following headline: "*Safety concerns grow over pharmacy-mixed drugs*." That article discussed growing concern over the fact that drugs produced in bulk by compounding pharmacies are not FDA approved and are not subject to the same oversight as drugs produced by pharmaceutical companies.[19]

In 2006 (six years before the catastrophe), the FDA conducted a survey of compounded drug products. They collected 36 samples from compounding pharmacies across the United States during unannounced visits. Twelve of the 36 samples (33%) failed analytical testing. The FDA survey concluded "*poor quality compounded drugs are a serious public health concern, as improperly compounded products have been linked to grave adverse events, including deaths.*"[20]

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[15] See **Exhibit 5**, Exhibit 32 to Schamberg Dep., p. 2, and **Exhibit 4,** PSC's Requests for Admissions No. 12.
[16] *Id.*
[17] See **Exhibit 5**, Exhibit 32 to Schamberg Dep., p. 2
[18] See **Exhibit 6**, Exhibit 35 to Deposition of Debra Schamberg, R.N. ("Schamberg Dep."), p. 4, and **Exhibit 4**, PSC's Requests for Admissions No. 1.
[19] See **Exhibit 7**, and **Exhibit 4**, PSC's Requests for Admissions No. 6.
[20] See **Exhibit 3**, Ex. 33 to Schamberg Dep., and **Exhibit 4**, PSC's Requests for Admissions No. 7.

In May 2007 (five years before the catastrophe), the FDA published an article titled: "*The Special Risks of Pharmacy Compounding*." That article highlighted numerous adverse events involving compounded products. It also warned of the emergence of large scale compounding operations that were clearly operating outside the bounds of traditional compounding practice.[21]

In 2010 (two years before the catastrophe), the FDA posted an educational video on YouTube regarding concerns over the quality of compounded drugs.[22]

On November 5, 2010 (about two years before the catastrophe), the American Society of Anesthesiologists, the American Society of Health-System Pharmacists ("ASHP") and other medical societies published a joint report regarding drug shortages. That report included an article written by the ASHP stating as follows:

> Compounding pharmacies have also pursued the production of drugs that are in short supply. Caution is warranted because preparations from these pharmacies may not meet applicable state or federal standards (e.g., United States Pharmacopeia chapter 797 or FDA labeling requirements). The sources of raw materials used by compounding pharmacies have been questioned, and apparent lapses in quality control have resulted in serious patient injury, including death.
>
> . . .
>
> Compounding pharmacies may also present patient risks; several deaths have been associated with improperly sterilized compounded products.[23]

In May 2012 (a few months before the meningitis catastrophe), the CDC published a report regarding fungal infections arising from medications obtained from a compounding pharmacy. That report advised that "contamination of compounded sterile preparations has caused outbreaks. Since 1990, FDA has learned of approximately 200 adverse events associated with 71 compounded products."[24]

C. NECC Had a Known History of Regulatory Non-Compliance.

Before the meningitis catastrophe, NECC had a history of adverse events relating to its operation as a compounding pharmacy. NECC was the subject of multiple complaints to and

[21] See **Exhibit 5**, Ex. 32 to Schamberg Dep., and **Exhibit 4**, PSC's Requests for Admissions No. 12.
[22] See **Exhibit 4**, PSC's Requests for Admissions No. 17.
[23] See **Exhibit 8** and **Exhibit 4**, PSC's Requests for Admissions No. 18.
[24] See **Exhibit 9**, and **Exhibit 4**, PSC's Requests for Admissions No. 19.

investigations by the FDA and the Massachusetts Board of Registration in Pharmacy ("MBP"). Those complaints and investigations often focused on unsterile conditions at NECC's facilities.[25] For example, the FDA issued a Warning Letter to NECC in 2006. The FDA letter details numerous problems at NECC including the sale of compounded drugs without patient-specific prescriptions. In addition, the FDA's Warning Letter stated that NECC was compounding copies of commercially available drugs, selling misbranded compounded drugs, and experiencing problems with storage and sterility. That warning letter was available to the Tennessee Defendants on the FDA's website long before the meningitis catastrophe.[26]

D. For Reasons of Price, Saint Thomas Neurosurgical Becomes NECC's Largest Customer.

Defendant Dr. Culclasure is the Medical Director of the Defendant Saint Thomas Neurosurgical.[27] Ms. Schamberg is the clinic's Facilities Director.[28] Dr. Culclasure and Ms. Schamberg made the decision for Saint Thomas Neurosurgical to purchase MPA from NECC.[29]

Saint Thomas Neurosurgical, Dr. Culclasure and Ms. Schamberg knew or should have known of the dangers of using compounded drugs generally and specifically products compounded by NECC. Nevertheless, they decided to purchase injectable steroids from NECC without undertaking any due diligence. They did nothing to ascertain the safety and quality of NECC's products. Instead, they decided to purchase the cheapest steroid available.[30]

In late 2010, Saint Thomas Neurosurgical began purchasing MPA from a supplier in Nashville, Tennessee known as Clint Pharmaceuticals.[31] The MPA that Saint Thomas Neurosurgical bought from Clint Pharmaceuticals did not come from a compounding pharmacy. Clint Pharmaceuticals only supplied steroids manufactured by FDA regulated pharmaceutical

[25] See **Exhibit 10**; The Committee on Energy and Commerce Majority Memorandum Re: Hearing on "The Fungal Meningitis Outbreak: Could It Have Been Prevented?", pp. 6 – 25.
[26] See **Exhibit 11**, Exhibit 306 to Deposition of Francis McAteer.
[27] See **Exhibit 12**, Transcript of Deposition of John Culclasure, M.D., at 15.
[28] See **Exhibit 1**, Schamberg dep. at 27 – 28.
[29] *Id.*, at 55 – 56.
[30] *Id.*, at 78-84.
[31] See **Exhibit 13**, Schamberg Dep. Exhibit 29, and **Exhibit 4**, PSC's Requests for Admissions No. 75.

companies.[32] All of the MPA purchased by Saint Thomas Neurosurgical from Clint Pharmaceuticals was FDA approved.[33]

In June of 2011, Saint Thomas Neurosurgical chose to stop buying FDA approved steroids through Clint Pharmaceuticals and start buying compounded MPA from NECC.[34] Saint Thomas Neurosurgical made that change when Clint Pharmaceuticals increased its price for FDA approved generic MPA from $6.49 per vial to $8.95 per vial.[35] Emails sent and received by Ms. Schamberg (Saint Thomas Neurosurgical's Facilities Director) establish that Saint Thomas Neurosurgical switched from purchasing FDA approved steroids to purchasing compounded steroids from NECC in order to save $2.46 per vial.[36]

According to invoices produced by Saint Thomas Neurosurgical, the clinic purchased two-thousand, five hundred (2,500) vials of MPA from NECC during a period of three months during the summer of 2012.[37] That extraordinary volume made Saint Thomas Neurosurgical NECC's largest customer by volume for the purchase of MPA during the critical three month period when NECC distributed tainted pharmaceuticals throughout the country.[38]

E. Saint Thomas Neurosurgical Did Nothing to Consider Safety When it Selected NECC.

The Defendants Culclasure and Schamberg decided to purchase compounded MPA for injection into patients' spines without doing anything to educate themselves about compounded

[32] See **Exhibit 14**, Deposition of Jeffrey Ebel at 14.
[33] *Id*.
[34] See **Exhibit 1**, Schamberg Dep. at 157-158.
[35] See **Exhibit 1**, Schamberg dep. at 85 and 136.
[36] See **Exhibit 15**, Exhibit 39 to Schamberg dep. at 10-14. (Saint Thomas Neurosurgical purchased MPA from Clint Pharmaceuticals at the price of $6.49 per 80mg vial. In May 2011, an NECC sales representative emailed Saint Thomas Neurosurgical's Facility Director, Ms. Schamberg, asking what price NECC would need to offer for MPA in order to gain Saint Thomas Neurosurgical's business. Ms. Schamberg replied that if NECC could get the price under $6.50 per vial, she would be willing to "talk" to NECC. On June 9, 2011, Clint Pharmaceuticals increased the price for MPA from $6.49 to $8.95 per vial, an increase of $2.46 per vial. Saint Thomas Neurosurgical was not willing to pay $8.95 per vial for MPA from Clint Pharmaceuticals if it could be procured more cheaply from NECC. Therefore, Ms. Schamberg emailed an NECC sales representative indicating that, if NECC would guarantee a price for MPA of $6.50 per 80mg vial, Saint Thomas Neurosurgical would be willing to do business with NECC. After NECC indicated its willingness to sell MPA for $6.50 per 1mL 80mg vial, Ms. Schamberg obtained approval from Dr. Culclasure to begin ordering from NECC. Saint Thomas Neurosurgical placed its first order for NECC steroids on June 10, 2011, one day after Clint Pharmaceuticals' price increase).
[37] See **Exhibit 4**, PSC's Requests for Admissions No. 90.
[38] See FDA List of NECC Customers by Product Information, available at: http://www.fda.gov/downloads/Drugs/DrugSafety/FungalMeningitis/UCM326145.xls.

medications in general or NECC in particular.[39] Culclasure and Schamberg testify that their decision to purchase compounded steroids from NECC included the following analysis and due diligence:

- zero research regarding the safety and risks of compounded medications;
- no review of FDA publications and warnings regarding the dangers of compounded drugs;
- zero review of medical literature regarding the risks of pharmacy compounding;
- no inquiries regarding previously reported deaths caused by compounded medications;
- no request to NECC for references;
- no effort to investigate NECC's regulatory history;
- no request to review NECC's sterility testing results;
- no attempt to identify or contact any NECC customers;
- zero effort to verify information contained in NECC's promotional literature; and
- no consultation with a pharmacist for advice about purchasing non-FDA approved compounded drugs.[40]

In fact, Culclasure and Schamberg never even bothered to Google NECC before they selected NECC to be Saint Thomas Neurosurgical's preferred supplier of injectable MPA.[41]

F. Saint Thomas Neurosurgical Incentivized its Medical Director to Administer as Many Steroids as Possible, as Quickly as Possible.

Saint Thomas Neurosurgical conducted a high volume epidural steroid injection practice, incentivizing its medical director to administer as many steroids as possible, as quickly as possible. In 2011 and 2012, Saint Thomas Neurosurgical performed an average of 450 to 500 epidural steroid injections each month. It performed roughly 5,000 epidural steroid injections each year.[42]

[39] See **Exhibit 1**, Schamberg Dep. at 78-84.
[40] *Id.*
[41] *Id.*
[42] See **Exhibit 1**, Schamberg dep. at 52-53, and **Exhibit 16**, Deposition of Scott Butler ("Butler Dep.") at 32.

The Medical Director of Saint Thomas Neurosurgical does not receive a salary.[43] He is paid a percentage of collections for the epidural injections that he gives. Specifically, Dr. Culclasure is paid an amount equal to sixty percent (60%) of the collections for each shot that he gives.[44] In other words, the more epidural steroids that Dr. Culclasure administers, the more money he makes.[45]

G. Saint Thomas Neurosurgical Sells MPA to Patients.

The testimony of the Defendant Debra Schamberg, Facilities Director for Saint Thomas Neurosurgical, clearly indicates that Saint Thomas Neurosurgical sells epidural steroids. Specifically, Ms. Schamberg testified as follows:

> Q. And St. Thomas Neurosurgical provides epidural steroids to patients in exchange for money, correct?
>
> A. That is correct.[46]

In addition, when Saint Thomas Neurosurgical administers epidural steroids to patients, it bills for those steroid injections separately from the services of the physicians who inject the medicine.[47] In other words, each time that Saint Thomas Neurosurgical administers an epidural steroid to a patient, it sends a separate invoice to the patient's private or public health insurer, such as Medicare or Blue Cross Blue Shield of Tennessee. Separate and apart from that invoice, Howell Allen Clinic (the neurosurgery group that owns ½ of Saint Thomas Neurosurgical) also sends an individual invoice to the patient's private or public insurer for the services of the physician who administered the injection.[48] In addition, contracts between Saint Thomas Neurosurgical and various payers state that Saint Thomas Neurosurgical's charges specifically include drugs provided to patients.[49]

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[43] See **Exhibit 12**, Culclasure dep. at 57.
[44] See **Exhibit 12**, Culclasure dep. at 57 and 66 – 67.
[45] See **Exhibit 16**, Butler dep. at 56-57.
[46] See **Exhibit 1**, Schamberg dep. at 55.
[47] See **Exhibit 16**, Butler dep. at 62.
[48] *Id.* at 72.
[49] See **Exhibit 17**, Exhibit 517 to Deposition of Cindy Williams.

Saint Thomas Neurosurgical's conduct after the meningitis catastrophe likewise demonstrates that Saint Thomas Neurosurgical is a "seller." In October 2012, Saint Thomas Neurosurgical sent a letter to NECC complaining that NECC's products were not "merchantable" and were no longer fit for "use/sale due to contamination."[50] That letter clearly indicates that Saint Thomas Neurosurgical views itself as a seller or distributor of MPA.[51]

[50] See **Exhibit 18**.
[51] *Id.*

ARGUMENT

A. Tennessee Law Requires Those Who Distribute or Sell Products to Stand Behind Those Products When a Manufacturer is Insolvent.

Plaintiffs assert strict product liability claims against the Tennessee clinics. Plaintiffs base those claims upon provisions of the Tennessee Products Liability Act of 1978, Tenn. Code Ann. § 29-28-101 *et seq.* That Act expressly authorizes claims for strict tort liability against sellers of defective or unreasonably dangerous products in certain circumstances, including when a product manufacturer is judicially declared insolvent.[52] The primary purpose of the seller liability statute "is to insure that where the manufacturer is insolvent, an injured party may look to a solvent seller for his losses."[53]

Under Tennessee law, a product seller "may be liable in strict liability for physical harm caused to a consumer by a defective product."[54] "[A] product liability action may be brought against a manufacturer or seller on strict liability grounds, with no proof of negligence, if the product causing injury to person or property 'is determined to be in a defective condition or unreasonably dangerous at the time it left the control of the manufacturer or seller.'"[55]

In *Owens*, the Tennessee Supreme Court described the public policy associated with holding product sellers strictly liable for harm caused by defective products:

> A primary purpose of this section is "to ensure that an injured consumer may maintain a strict liability action against whomever is most likely to compensate him for his injuries." When the manufacturer is not amenable to service of process or is insolvent, an injured consumer can assert liability against the "faultless" seller. If, under these circumstances, the seller were not held to be jointly liable for the plaintiff's damages, then, contrary to the products liability statute, the injured consumer would be left with no remedy.[56]

The *Owens* Court also explained that innocent tort victims "who are powerless to protect themselves" should not bear "the burden of loss" resulting from a defective

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[52] Tenn. Code Ann. § 29-28-106(5).
[53] *Seals v. Sears, Roebuck and Co., Inc.*, 688 F. Supp. 1252, 1256 (E. D. Tenn. 1988).
[54] *Nye v. Bayer Cropscience, Inc.*, 347 S.W.3d 686, 692 (Tenn. 2011)(citing RESTATEMENT (SECOND) OF TORTS § 402A (1965)).
[55] *Id.* at 692-93 (quoting Tenn. Code Ann. § 29-28-105(a)).
[56] *Id*. at 432 (citations omitted).

product.[57] That burden should be borne jointly by all parties involved in bringing the product to consumers in the marketplace.[58]

On July 24, 2013, the Honorable Henry J. Boroff, Judge of the United States Bankruptcy Court for this district, declared that the product manufacturer, NECC, is insolvent. Accordingly, injured Tennessee tort victims are entitled to assert strict product liability claims against those who distributed or sold defective NECC products in Tennessee.[59]

B. Saint Thomas Neurosurgical Meets the Statutory Definition of "Seller" Because it Distributed or Sold MPA.

The Tennessee Products Liability Act defines the term "seller" broadly. "Seller" includes any retailer, wholesaler, *or distributor* of a product, and it includes any entity in the business of selling a product, whether such sale is for resale, or for use or consumption.[60] Specifically, the statute provides:

> "Seller" includes a retailer, wholesaler, or distributor, and means any individual or entity engaged in the business of selling a product, whether such sale is for resale, or for use or consumption. "Seller" also includes a lessor or bailor engaged in the business of leasing or bailment of a product.[61]

Without question, Saint Thomas Neurosurgical distributed MPA to patients. Testimony from several officers of Saint Thomas Neurosurgical reveals that the clinic conducted a high volume epidural steroid injection practice, incentivizing its medical director to inject as many steroids as possible, as quickly as possible. In 2011 and 2012, Saint Thomas Neurosurgical performed an average of 450 to 500 epidural steroid injections per month. It performed roughly 5,000 epidural steroid injections each year.[62] In addition, the clinic's medical director does not receive a salary.[63] He is paid a percentage of the collections generated by epidural steroid injections that he gives. Specifically, the Defendant Dr. Culclasure is paid an

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[57] *Owens*, 915 S.W.2d at 431.
[58] *Id*. at 431-433.
[59] *Seals v. Sears, Roebuck and Co., Inc.*, 688 F. Supp. 1252, 1256 (E. D. Tenn. 1988); and Tenn. Code Ann. §§ 29-28-106.
[60] Tenn. Code Ann. § 29-28-102(7).
[61] *Id*.
[62] See **Exhibit 1**, Schamberg dep. at 52-53, and **Exhibit 16**, Butler dep. at 32.
[63] See **Exhibit 12**, Culclasure dep. at 57.

amount equal to sixty percent (60%) of the collections from each shot that he gives.[64] The more epidural steroids that Dr. Culclasure administers, the more money he makes.[65]

The undisputed facts likewise demonstrate that Saint Thomas Neurosurgical sells the steroids that it distributes. For example, when Saint Thomas Neurosurgical administers epidural steroids to patients, it bills for those steroid injections separately from the services of the physician who injects the medicine.[66] When the clinic administers an epidural steroid injection to a patient, it sends a separate bill to the patient's private or public health insurer, such as Medicare or Blue Cross Blue Shield of Tennessee. Separate and apart from that invoice, the Defendant Howell Allen Clinic (the neurosurgery group that owns ½ of Saint Thomas Neurosurgical) also sends an individual invoice to the patient's private or public insurer for the services of the physician who administered the injection.[67]

The testimony of the Defendant Debra Schamberg, Facilities Director for Saint Thomas Neurosurgical, likewise indicates that Saint Thomas Neurosurgical sells epidural steroids. Specifically, Ms. Schamberg testified as follows:

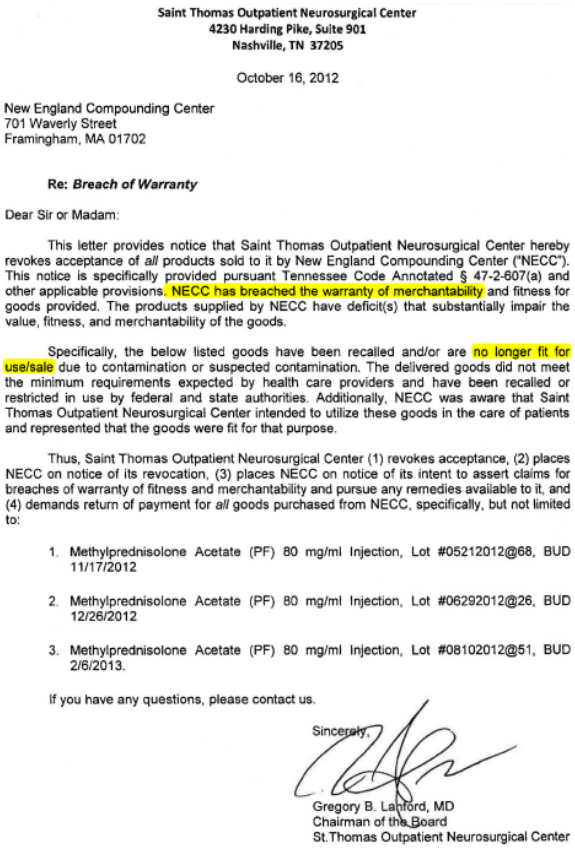
> Q. And St. Thomas Neurosurgical provides epidural steroids to patients in exchange for money, correct?
>
> A. That is correct.[68]

In addition, Saint Thomas Neurosurgical's contracts with payers establish that the clinic is paid for drugs that it distributes. One such contract specifically provides that the "global fee" paid by Blue Cross to Saint Thomas Neurosurgical includes payment for drugs. [69]

Saint Thomas Neurosurgical's status as a seller is further confirmed by a letter that it sent to NECC on October 16, 2012. In that letter, Saint Thomas Neurosurgical states that NECC breached its warranty of "merchantability" and supplied products that "are no longer fit for

[64] See **Exhibit 12**, Culclasure dep. at 57 and 66 – 67.
[65] See **Exhibit 16**, Butler dep. at 56-57.
[66] *Id*. at 62.
[67] *Id*. at 72.
[68] See **Exhibit 1**, Schamberg dep. at 55.
[69] See **Exhibit 17.**

use/sale due to contamination." Specifically, the letter, which was signed by the Chairman of Saint Thomas Neurosurgical's Board of Governors, provides:



Saint Thomas Outpatient Neurosurgical Center
4230 Harding Pike, Suite 901
Nashville, TN 37205

October 16, 2012

New England Compounding Center
701 Waverly Street
Framingham, MA 01702

Re: *Breach of Warranty*

Dear Sir or Madam:

This letter provides notice that Saint Thomas Outpatient Neurosurgical Center hereby revokes acceptance of *all* products sold to it by New England Compounding Center ("NECC"). This notice is specifically provided pursuant Tennessee Code Annotated § 47-2-607(a) and other applicable provisions. NECC has breached the warranty of merchantability and fitness for goods provided. The products supplied by NECC have deficit(s) that substantially impair the value, fitness, and merchantability of the goods.

Specifically, the below listed goods have been recalled and/or are no longer fit for use/sale due to contamination or suspected contamination. The delivered goods did not meet the minimum requirements expected by health care providers and have been recalled or restricted in use by federal and state authorities. Additionally, NECC was aware that Saint Thomas Outpatient Neurosurgical Center intended to utilize these goods in the care of patients and represented that the goods were fit for that purpose.

Thus, Saint Thomas Outpatient Neurosurgical Center (1) revokes acceptance, (2) places NECC on notice of its revocation, (3) places NECC on notice of its intent to assert claims for breaches of warranty of fitness and merchantability and pursue any remedies available to it, and (4) demands return of payment for *all* goods purchased from NECC, specifically, but not limited to:

1. Methylprednisolone Acetate (PF) 80 mg/ml Injection, Lot #05212012@68, BUD 11/17/2012
2. Methylprednisolone Acetate (PF) 80 mg/ml Injection, Lot #06292012@26, BUD 12/26/2012
3. Methylprednisolone Acetate (PF) 80 mg/ml Injection, Lot #08102012@51, BUD 2/6/2013.

If you have any questions, please contact us.

Sincerely,

Gregory B. Lanford, MD
Chairman of the Board
St.Thomas Outpatient Neurosurgical Center

Based upon those undisputed facts, Saint Thomas Neurosurgical is a seller or distributor of MPA, and it meets the broad statutory definition of "seller" as articulated in Tenn. Code Ann. § 29-28-102(7).

C. Joint and Several Liability Applies to All Parties Involved with Making, Testing or Distributing Defective Products.

In ruling upon the Tennessee Defendants' motions to dismiss, this Court correctly held that the Tennessee Plaintiffs are allowed to prosecute claims for strict product liability against the Tennessee Defendants.[70] This Court found that the Tennessee Healthcare Liability Act does not prevent the Tennessee Plaintiffs from asserting separate claims for strict product liability under the Tennessee Products Liability Act.[71]

[70] Memorandum of Decision entered August 29, 2014, Doc. No. 1360.
[71] *Id.* at 25-31.

As explained by the Tennessee Supreme Court in *Owens*, joint and several liability applies to manufacturers, sellers and distributors of defective products as well as to all parties within the "chain of distribution."[72] In other words, fault at trial must be assigned to the product as a single unit or share. Fault cannot be assigned separately to manufacturers, sellers, distributors and other parties who played a role in bringing the product to market:

> Consequently, joint and several liability against parties in the chain of distribution of a product is essential to the theory of strict products liability. Since strict liability does not require proof of negligence, but only that the product was defective or unreasonably dangerous, parties in the chain of distribution must be treated as a single unit for the purpose of determining and allocating fault.[73]

Although Tennessee courts have not defined the scope of the term "chain of distribution," the term is defined broadly in other jurisdictions. All parties who play an integral role in making, testing, marketing, or distributing the product are considered part of the distribution chain.[74] "[N]o precise legal relationship to the manufacturer or ultimate seller is required before the courts will impose strict liability; it is the defendant's participation, for personal profit or other benefit, with the product and the enterprise that created consumer demand for it that calls for the imposition of strict liability."[75] As observed by the United States District Court for the Eastern District of Kentucky in *Taylor v. Gen. Motors, Inc.*, 537 F.Supp.949, 954 (E.D.Ky. 1982):

> Some courts have applied strict liability principles to any entity which is "an integral part of the composite business enterprise which placed the defective (product) in the stream of commerce." (citation omitted).[76]

Thus, entities that participate in making, marketing and testing a product are considered part of the distribution chain for strict product liability purposes.[77]

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[72] *Owens*, 915 S.W.2d at 432.
[73] *Id*.
[74] *See* 72A C.J.S. Products Liability § 62; *Gunderson v. Sani-Kem Corporation*, 674 S.W.2d 665 (Mo.Ct.App. 1984); *Taylor v. Gen. Motors, Inc.*, 537 F.Supp.949, 954 (E.D.Ky. 1982); *Wimberly v. Derby Cycle Corp.*, 56 Cal.App.4th 618, 628 (1997); *Kasel v. Remington Arms Co.*, 24 Cal.App.3d 711, 725 (1972); and *Zamora v. Mobil Corp.*, 104 Wash.2d 199, 207 (1985).
[75] 72A C.J.S. Products Liability § 62.
[76] *Taylor v. Gen. Motors, Inc.*, 537 F.Supp.949, 954 (E.D.Ky. 1982).

In the present litigation, the Tennessee Defendants seek to attribute fault at trial to any and every other party who participated in making, marketing, testing or assuring the sterility of the subject product.[78] For example, the Tennessee Defendants attempt to attribute fault to NECC and its owners and/or employees, *i.e.* Barry Cadden, Glenn Chin, Douglas Conigliaro, etc.[79] They seek to attribute fault to those who participated in testing the product for sterility, i.e., ARL BioPharma, Inc., and to those involved in designing, constructing and cleaning NECC's "clean room", i.e., Liberty Industries, Unifirst, Victory, and Scientific Air Analysis.[80] In addition, the Tennessee Defendants attempt to attribute fault to private and governmental entities that inspected NECC's compounding processes, *i.e.*, Massachusetts Board of Registration in Pharmacy, FDA, and Pharmacy Support, Inc. The Tennessee Defendants also seek to place fault upon those involved in marketing the product, i.e. Medical Sales Management and John Notarianni.[81] All of those "up-stream" parties are part of the distribution chain because all of those parties played a role in the manufacture, distribution or sale of the product.

If Saint Thomas Neurosurgical, as a product distributor and seller, is permitted to attribute fault at trial to up-stream parties who were involved with making, marketing, or testing the subject product, such would render the Tennessee Supreme Court's holding in *Owens* completely meaningless. Permitting such blame shifting at trial would cause the burden of loss to fall upon innocent victims rather than the parties who profited from distributing and selling the defective product. Such a result would be contrary to Tennessee law and contrary to basic precepts of justice.

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[77] *Taylor* at 951 (General Motors tested subject product and was found to be within chain of distribution); *SSP Partners v. Gladstrong Investments (USA) Corp.*, 169 S.W.3d 27 (2005) (company that marketed product found to be apparent manufacturer and within distribution chain); *Ghoinis v. Deer Valley Resort*, 839 F.Supp.789 (1993)(lessor who marketed product could be strictly liable); *Crowe v. Public Blvd. Comm. of Chicago*, 74 Ill.2d 10 (Ill.1978) (lessor who marketed product held within chain of distribution).

[78] Attached as **Exhibit 19** is a chart listing parties alleged by the Tennessee Defendants to be comparatively at fault along with a description of those parties' alleged involvement with the product. The chart was prepared from allegations contained in the Tennessee Defendants' Answers to the Master Complaint.

[79] *Id.*

[80] *Id.*

[81] *Id.*

CONCLUSION

Based upon the undisputed facts discussed above, this Court should hold that Saint Thomas Neurosurgical falls within the statutory definition of "seller" as articulated in Tenn. Code. Ann. § 29-28-102(7). Under the controlling Tennessee Supreme Court precedent in *Owens*, this Court should rule that fault for harm caused by the product will be allocated as a single share at trial, and fault cannot be allocated separately to upstream parties within the distribution chain.

Respectfully submitted,

/s/ **George Nolan**

George Nolan (B.P.R. No. 14974)
LEADER, BULSO & NOLAN, PLC
414 Union Street, Suite 1740
Nashville, Tennessee 37219
(615) 780-4111
gnolan@leaderbulso.com

As designated counsel on behalf of the Plaintiffs' Steering Committee

Thomas M. Sobol
Kristen Johnson Parker
HAGENS BERMAN SOBOL SHAPIRO LLP
55 Cambridge Parkway, Suite 301
Cambridge, MA 02142
Telephone: (617) 482-3700
Facsimile: (617) 482-3003
tom@hbsslaw.com
kristenjp@hbsslaw.com

Plaintiffs' Lead Counsel

Elizabeth J. Cabraser
Mark P. Chalos
LIEFF CABRASER HEIMANN & BERNSTEIN, LLP
275 Battery Street, 29th Floor
San Francisco, CA 94111
Telephone: (415) 956-1000
Facsimile: (415) 956-1008
ecabraser@lchb.com
mchalos@lchb.com

Federal/*State Liaison*

Marc E. Lipton
LIPTON LAW
18930 W. 10 Mile Road
Southfield, MI 48075
Telephone: (248) 557-1688
Facsimile: (248) 557-6344
marc@liptonlawcenter.com

Kim Dougherty
JANET, JENNER & SUGGS, LLC
31 St. James Ave., Suite 365
Boston, MA 02116
Telephone: (617) 933-1265
kdougherty@myadvocates.com

Patrick T. Fennell
CRANDALL & KATT
366 Elm Avenue, S.W.
Roanoke, VA 24016

Mark Zamora
ZAMORA FIRM
6 Concourse Way, 22nd Floor
Atlanta, GA 30328

Telephone: (540) 342-2000
pfennel@crandalllaw.com

Telephone: (404) 451-7781
Facsimile: (404) 506-9223
marc@markzamora.com

J. Gerard Stranch, IV
Benjamin A. Gastel
BRANSTETTER, STRANCH & JENNINGS PLLC
227 Second Avenue North, 4th Floor
Nashville, TN 37201
Telephone: (615) 254-8801
Facsimile: (615) 255-5419
gerards@branstetterlaw.com

Plaintiffs' Steering Committee

CERTIFICATE OF SERVICE

I, George Nolan, hereby certify that on October 6, 2015, I caused a copy of the foregoing to be filed electronically via the Court's electronic filing system. Those attorneys who are registered with the Court's electronic filing system may access these filings through the Court's system, and notice of these filings will be sent to these parties by operation of the Court's electronic filing system.

/s/ **George Nolan**
George Nolan